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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/782,306 | 02/14/2001 | Uwe Wenzel | 51202 | 2453 |

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| EXAMINER | |
|---|---|
| KHARE, DEVESH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/782,306 | WENZEL ET AL. | |
| | Examiner | Art Unit | |
| | Devesh Khare | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 2* is/are allowed.

6)☒ Claim(s) *3 and 4* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



RC

Applicant's amendments and remarks filed on 05/31/05 are acknowledged. Claims 1 and 2 have been amended. New claim 13 has been added. Claims 5-12 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The rejection under 35 U.S.C. 112, second paragraph of the Office Action dated 12/28/2004 has been overcome through applicants' amendment to the claims.

Claims 1-4 and 13 are currently being examined.

**Minor objections**

Claim 13 is objected to because of the following informalities:

The Markush groups for the sugar substituent include non-sugar substituents (hydrogen, hydroxy and methoxy). The said non-sugar substituents should be deleted.

Appropriate correction is required.

***35 U.S.C. 112, first paragraph rejection***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3 and 4 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for flavone effects on cell-cycle arrest and apoptosis in HT-29 cells, does not reasonably provide enablement for a method of inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis in a patient comprising administering to a patient a therapeutically effective amount of a compound (I) or

compound (II). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine how to a therapeutically effective amount of a compound (I) or compound (II)

can be used in a patient for inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis. There has not been provided adequate guidance in the written description for accomplishing such, as only the flavone effects on gene expression in HT-29 cells were described and no inhibition of COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis in a patient with the compound (I) or Compound (II) is described.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, Nair et al. (prior art cited in the Office Action dated 2/13/2003) disclose the importance of plant-derived compounds as anti-inflammatory agents by inhibiting prostaglandin synthesis or cyclooxygenase (COX) enzymes (see col. 1, lines 33-35 and col. 2, lines 43-46). The art at the time the invention was made fails to establish predictability with regard to the specific flavone compounds (I) and (II) of the applicant's.

With regard to factors (3) and (7), it is noted that while there are some working examples (1-3) on the cell culture of HT-29 cells, semi-quantitative RT-PCR and flavone effects on gene expression in HT-29 cells; and claims 1,2 and 13 are directed to a composition for inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis comprising a therapeutically effective amount of the compound of formula (I) or (II), it is not seen as sufficient to support the breath of the claims wherein a therapeutically effective amount of a compound (I) or compound (II) are used in a patient for inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis.

With regard to factor (8), the relative skill in the art as it relates to a method of inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis in a patient comprising administering to a patient a therapeutically effective amount of a compound (I) or compound (II), is that of a Ph.D. or M.D. level.
Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims 3 and 4, which encompass a method of inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis in a patient comprising administering to a patient a therapeutically effective amount of a compound (I) or compound (II). It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of a method of inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis in a patient comprising administering to a patient a therapeutically effective amount of a compound (I) or compound (II), would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

2. A review of the prior art revealed no references that could be appropriately applied on claims 1,2 and 13. Claims 1,2 and 13 directed to a composition for inhibiting COX-2 biosynthesis or COX-2 biosynthesis and NFxB biosynthesis comprising a therapeutically effective amount of the compound of formula I or II, which is not taught or fairly suggested by the prior art of the record.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
August 5,2005

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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